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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,630	07/31/2001	Mark A. Sanner	PC10825A	6400

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EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/05/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/919,630

Applicant(s)

SANNER ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-33 is/are pending in the application.
- 4a) Of the above claim(s) 9,11 and 17-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-8,10, 12-14 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment filed 26 August 2002 has been considered and is entered into the case as Paper No. 8.

Claims 1-14 and 16-33 are currently pending in the instant application. Claims 9, 11 and 17-33 are withdrawn from further consideration as being drawn to non-elected subject matter. Claims 15 and 34-57 have been cancelled in Paper No. 8. Claims 1-8, 10, 12-14 and 16 are objected to.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-16 and the species of example 1, page 48 of the specification, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that:

Applicants have reduced the extent of the search and examination that the Examiner would have to perform by canceling the claims of Groups III and V,

That although pharmaceutical compositions comprising a different active ingredient may be able to treat the same indications, such compositions do not treat the same indications in the same way as the instant compositions,

A search of the compounds of formula 1 would generally be able to uncover any art pertaining to pharmaceutical compositions comprising compounds of formula 1,

That although the indications treatable by such methods may be treatable by a different active ingredient, such treatment is not the same treatment because it would involve a different mechanism,

And the claims of groups I, II and IV share a common core "principle", the use of

a compound that has activity inhibiting cdk5,

Applicants traversal of the election of a single disclosed species is on the ground(s) that:

All of the compounds of formula 1 share a common structural core, and all of the methods of treatment have in common utilization of the same mechanism of inhibition of cdk5 and/or GSK3beta,

To require applicant to file a separate patent application on every indication and/or on every compound that is part of the applicant's invention would be unduly burdensome, and perhaps cost prohibitive, on the applicant.

This is not found persuasive because the groups identified as general areas are independent or distinct as the compositions of groups II and III may utilize other active ingredients other than those of group I, the compositions of groups II and III differ materially in makeup (e.g. active ingredients), and the products are capable of more than one use as is clearly evident from the instant specification and the methods of use may be practiced with products other than those of the instant product claims. The methods of group IV and V utilize materially different products. Although applicants have reduced the extent of the search required by canceling claims, each group is directed to art recognized divergent subject matter, which requires different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner. Also, it is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner the

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authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. Rather, applicant has argued a lack of unity standard (i.e. the arguments discussing the common core), which does not address the premise of the restriction requirement. Notwithstanding that lack of unity is not the basis for this restriction requirement, a lack of unity standard requires that the claims contain a special technical feature that defines a contribution over the art. Here the claims (1-17, 19, 21-28, 31-33) contain substituted 4-amino imidazole that does not define a contribution over the art as there are numerous references, such as US Patent No. 6150352, which contain such a group. Claims 18, 20 and 29-30 contain a cdk5 inhibitor that does not define a contribution over the art. So, here we have claims, which involve more than one independent or distinct invention. Under 35 U.S.C. 121, the claims may be restricted and the examination limited to a restricted invention. There is no argument or evidence to the contrary. Accordingly, restriction as has been presented in this application is proper. The requirement is still deemed proper and is therefore made FINAL.

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With the identification of the above noted species, the examiner, as indicated in the restriction requirement of Paper No. 8, will identify a generic concept, inclusive of said species, for examination. The generic concept is that of the compound of formula 1 as found in claim 1 wherein:

R1 is a (C3-C8)cycloalkyl, (C4-C8) cycloalkenyl, (C5-C11)bicycloalkyl, (C7-C11)bicycloalkenyl, or (C6-C14)aryl; and wherein R1 is optionally substituted with from one to six substituents R5,

R2 is as found in claim 1,

R3 is as found in claim 1,

R4 is quinolyl; wherein R4 is optionally substituted with from one to three substituents R6 ,

R5 is as found in claim 1,

R6 is as found in claim 1,

Each R7, R8, and R9 is independently selected from H, straight chain or branched (C1-C8)alkyl, straight chain or branched (C2-C8)alkenyl, straight chain or branched (C2-C8 alkynyl), (C3-C8)cycloalkyl, (C4-C8)cycloalkenyl, (C5-C11)bicycloalkyl, (C7-C11)bicycloalkenyl, (C6-C14)aryl, wherein R7, R8, and R9 are each independently optionally substituted with from one to six substituents independently selected from that as found in claim 1,

Each R10, R11, and R12 is independently selected from H, straight chain or branched (C1-C8)alkyl, straight chain or branched (C2-C8)alkenyl, straight chain or branched (C2-C8 alkynyl), (C3-C8)cycloalkyl, (C4-C8)cycloalkenyl, (C5-C11)bicycloalkyl, (C7-

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C11)bicycloalkenyl, (C6-C14)aryl, wherein R10, R11, and R12 are each independently optionally substituted with from one to six substituents independently selected from that as found in claim 1,

Each R13, R14, and R15 is independently selected from H, straight chain or branched (C1-C8)alkyl, straight chain or branched (C2-C8)alkenyl, straight chain or branched (C2-C8 alkynyl), (C3-C8)cycloalkyl, (C4-C8)cycloalkenyl, (C5-C11)bicycloalkyl, (C7-C11)bicycloalkenyl, (C6-C14)aryl, wherein R13, R14, and R15 are each independently optionally substituted with from one to six substituents independently selected from that as found in claim 1,

Each R16, R17, and R18 is independently selected from H, straight chain or branched (C1-C8)alkyl, straight chain or branched (C2-C8)alkenyl, straight chain or branched (C2-C8 alkynyl), (C3-C8)cycloalkyl, (C4-C8)cycloalkenyl, (C5-C11)bicycloalkyl, (C7-C11)bicycloalkenyl, (C6-C14)aryl, and  
n is 0, 1, 2 or 3.

The remaining subject matter of claims 1-8, 10, 12-14 and 16 and the subject matter of claims, 11 and 17-33 stands withdrawn, 37 CFR 1.142 (b), as being for non-elected inventions. The withdrawn subject matter of the claims is properly restricted as said subject matter differs materially in structure and element from the elected subject matter so as to be patentably distinct, i.e. a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

Additionally, the fields of search are not co-extensive.

Accordingly, the claims are drawn to more than a single invention and restriction as has been required is proper, 37 CFR 1.142 (a). It is noted, however, that if the product claims of invention I are subsequently found allowable (i.e. presented drawn solely to the elected subject matter as indicated supra), the withdrawn method claims, which depend from or otherwise includes all the limitations of the allowable product claims will be rejoined (i.e. claims 21-28 and 32-33 of group IV).

### ***Claim Objections***

Claims 1-8, 10, 12-14 and 16 are objected to as containing non-elected subject matter. The claims presented drawn solely to the elected subject matter as indicated supra, would appear allowable.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.



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A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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